Gateway™
PTA Balloon Catheter

Instructions for Use

Boston Scientific

Manufactured By:
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Gateway™ PTA Balloon Catheter

Instructions for Use

Humanitarian Device: The Wingspan Stent System with Gateway PTA Balloon Catheter is Authorized by Federal law for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system.

The effectiveness of this device for this use has not been demonstrated.

DEVICE DESCRIPTION

The Gateway™ PTA Balloon Catheter is an over-the-wire co-axial catheter with a balloon near the distal tip. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires (≤ 0.014 in./0.36 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter is coated on the exterior with BIOSLIDE™, a hydrophilic surface that reduces friction during manipulation. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the stenosis. Marker bands, in conjunction with fluoroscopy, aid in the placement of the catheter balloon segment. The proximal portion of the catheter includes one Luer-lock side port connected to the outer lumen. The wire lumen has a port for use with appropriate neurovascular guidewires. The catheter is advanced through the neurovascular anatomy for dilating stenotic portions of intracranial arteries.

INDICATION FOR USE

The Gateway PTA Balloon Catheter is indicated for balloon dilation of the stenotic portion of intracranial arteries prior to stenting for the purpose of improving intracranial perfusion.

CONTRAINDICATIONS

The Gateway PTA Balloon Catheter is contraindicated for use in:

- Patients in whom antiplatelet and/or coagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents effective angioplasty.

WARNINGS

- Since the use of this device carries the associated risk of subacute thrombosis, vascular complication and/or bleeding events, judicious selection of patients is necessary.
- Only physicians who have received appropriate training should perform intracranial angioplasty.
- Angioplasty and stenting procedures should only be performed at hospitals where emergency intracranial surgery can be readily performed in the event of a potentially injurious or life-threatening complication.

PRECAUTIONS

General Precautions

- Store in a dry, dark, cool place. Do not resterilize.
- Note product "Use By" date.

Preparation Precautions

- Follow the Gateway PTA Balloon Catheter preparation and use instructions carefully, as described on page 6, Preparation.

- **Do not prepare or pre-inflate the balloon** other than as directed. Use the balloon purging technique described in this *Instructions for Use*.
- Typical antiplatelet and anticoagulation regimen used for interventional intracranial procedure is an important adjunct to balloon angioplasty treatment. Do not use the Gateway PTA Balloon Catheter in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated. Vessel thrombosis may occur during the procedure if proper antiplatelet and anticoagulation therapy is not administered.

Procedure Precautions

- Angioplasty may lead to dissection of the vessel and may cause other complications (vasospasm/acute closure) of the vessel requiring additional intervention (i.e., further dilation, placement of stents).
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon because it may cause uneven inflation and complications.
- If unexpected difficulty is experienced during inflation, do not continue; remove the device and do not attempt to use it.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the lesser of the vessel diameters just proximal and distal to the stenosis.
- Do not use a guidewire having a diameter greater than 0.014 in/0.36 mm.
- When the delivery catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Infusion of any medium other than a flush of heparinized normal saline through the guidewire lumen may compromise device performance.
- Do not attempt to reposition a partially deployed balloon. Attempted repositioning of a partially deployed balloon may result in severe vessel damage.
- Balloon pressures should be monitored during inflation. **Do not exceed rated burst pressure indicated on the product label.** Use of pressures higher than those specified on the product label may result in a ruptured balloon and potential intimal damage and dissection. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence interval) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Before withdrawing the device, visually confirm complete balloon deflation by fluoroscopy. If the balloon has already been inflated and difficulty is experienced deflating, connect a large-barrel syringe and manually attempt to deflate the device.

Table 1: Typical Gateway System Balloon Compliance

Pressure (atm/bar)	Balloon Size									
	1.50mm	**2.0mm**	**2.25mm**	**2.50mm**	**2.75mm**	**3.0mm**	**3.25mm**	**3.50mm**	**3.75mm**	**4.0mm**
1.0	1.39	1.85	2.09	2.29	2.55	2.77	3.02	3.24	3.50	3.75
2.0	1.41	1.88	2.12	2.34	2.59	2.82	3.07	3.29	3.55	3.80
3.0	1.43	1.91	2.15	2.38	2.63	2.86	3.11	3.35	3.60	3.85
4.0	1.46	1.94	2.19	2.42	2.67	2.91	3.16	3.40	3.65	3.90
5.0	1.48	1.97	2.22	2.46	2.71	2.95	3.20	3.45	3.70	3.95
6.0 Nominal	**1.50**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**3.75**	**4.00**
7.0	1.52	2.03	2.28	2.54	2.79	3.05	3.30	3.55	3.80	4.05
8.0	1.55	2.06	2.31	2.58	2.83	3.09	3.34	3.60	3.85	4.10
9.0	1.57	2.09	2.35	2.62	2.87	3.14	3.39	3.65	3.90	4.15
10.0	1.59	2.12	2.38	2.67	2.91	3.18	3.43	3.71	3.95	4.20
11.0	1.61	2.15	2.41	2.71	2.95	3.23	3.48	3.76	4.00	4.25
12.0	1.63*	2.19*	2.44	2.75	2.99	3.28	3.52	3.81*	4.05*	4.31*
13.0	1.66	2.22	2.47	2.79	3.03	3.32	3.57	3.86	4.10	4.36
14.0	1.68	2.25	2.51*	2.83*	3.07*	3.37*	3.61*	3.91	4.15	4.41
15.0	1.70	2.28	2.54	2.87	3.11	3.41	3.66	3.96	4.20	4.46
16.0			2.57	2.91	3.15	3.46	3.70			
17.0			2.60	2.95	3.19	3.50	3.75			
18.0			2.63	2.99	3.23	3.55	3.79			

* Rated Burst Pressure. Do not exceed.

35

POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) may be associated with the use of an intracranial angioplasty in stenotic lesions of the intracranial arteries:

- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Distal emboli (air, tissue, or thrombotic emboli)
- Hematoma
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia/Infarct
- Perforation
- Pseudoaneurysm, (femoral and intracranial)
- Restenosis of the dilated vessel
- Spasm
- Stroke/TIA
- Total occlusion of the intracranial artery

PROCEDURE STEPS

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the balloon catheter, to verify proper function. Verify that the catheter, and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.

Materials Required (Not included in the Gateway Package)
Material

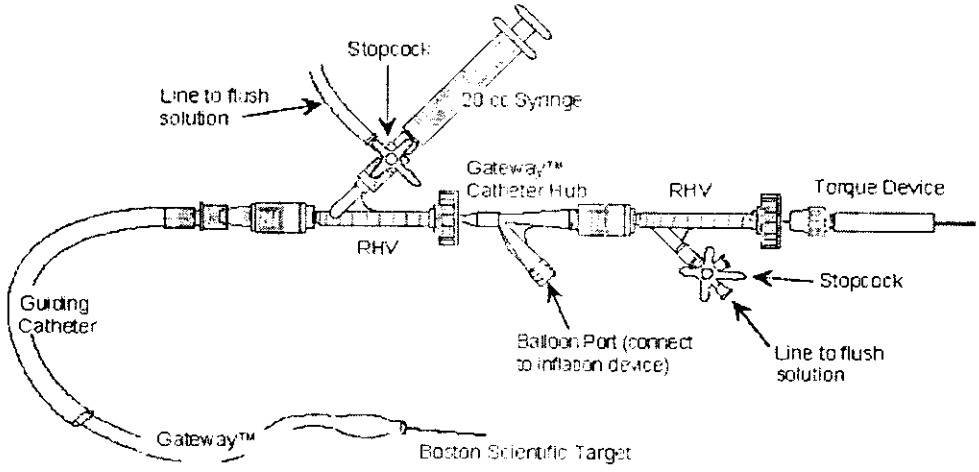
- Appropriate guide catheter(s) (0.064 in/1.63 mm minimum ID)
- 1000U/500ml (cc) Heparinized Normal Saline (HepNS)
- 0.014 in./0.36 mm, neurovascular exchange length guidewire(s)
- Rotating Hemostasis Valve (RHV) and adapter
- 60% contrast diluted 1:1 with normal saline
- Appropriate arterial sheath and dilator set and guide catheters for femoral approach
- 20 ml (cc) syringe with Luer-lock
- Inflation device with manometer
- Three-way stopcock

CAUTION

In order to achieve optimal performance of Gateway™ catheters and Boston Scientific steerable guidewires and to maintain the lubricity of the BIOSLIDE™ surface, it is critical that a continuous flow of appropriate flush solution be maintained between a) the Gateway catheter and guide catheter, and b) the Gateway catheter and any intraluminal device. In addition, flushing aids in preventing contrast crystal formation and/or clotting on both the guidewire and inside the catheter lumen.

The recommended continuous flush set up as illustrated requires two stopcocks and two rotating hemostatic valves (RHV); the RHV's provide a fluid tight seal and are attached to the guide catheter Gateway catheter. The stopcocks attach to the RHV sidearms, which become infusion ports for appropriate flush or contrast medium injection.

PREPARATION



Inflation Device Preparation

Step	Action
1	Prepare the inflation device according to the manufacturer's instructions.

Balloon Catheter Selection

Step	Action
1	The inflation diameter of the balloon must not exceed the diameter of the artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired balloon catheter, use a smaller diameter catheter to pre-dilate the lesion to facilitate passage of a more appropriate sized balloon catheter.

Balloon Catheter Preparation

Step	Action
1	Remove the catheter from the protective hoop.
2	Remove the balloon protector and stylet by grasping the balloon catheter just proximal to the balloon and with the other hand, gently grasp the proximal section of the balloon protector and slide distally.
3	Prepare the balloon catheter for purging. Fill a Luer-lock syringe with 3 ml (cc) of contrast medium. Use only appropriate balloon inflation medium. **Do not use air or any gaseous medium to inflate the balloon.**
4	Connect a three-way stopcock to the port fitting on the balloon catheter. Flush through the stopcock.
5	Connect the syringe to the stopcock.

6 Hold the syringe with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger.
7 Remove the syringe and evacuate all air from the barrel.
8 Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If air bubbles persist, do not use the device.
9 Disconnect the syringe.
10 Carefully wet the hydrophilic outer shaft of the balloon catheter.

Inflation Device Connection to Catheter

Step	Action
1	To remove any air lodged in the distal Luer fitting of the inflation device, purge approximately 1ml (cc) of contrast medium.
2	By applying positive pressure to the balloon before disconnection the syringe used in preparation, a meniscus will appear in the balloon port when the syringe is removed. Verify that a meniscus of contrast medium is evident in both the catheter balloon port and the inflation device connection. Securely couple the inflation device to the balloon port of the balloon catheter.

DEPLOYMENT PROCEDURE

Step	Action
1	Prepare the vascular site according to standard practice.
2	Prepare the balloon catheter and guidewire as follows: a) Flush the balloon catheter guidewire lumen. b) Introduce the guidewire, flexible end first, into the straight (back) port of the manifold. To avoid kinking, advance the guidewire slowly in small increments to the end of the balloon catheter. If desired, leave the distal end of the guidewire inside the catheter lumen for protection.
3	Loosen the knob on the hemostatic adapter.
4	With the balloon fully deflated, carefully insert the balloon catheter through the hemostatic adapter valve into the Luer fitting of the guide catheter. Tighten the hemostatic adapter knob to create a seal around the balloon catheter without inhibiting movement of the catheter; this will allow continuous recording of the proximal arterial pressure. Caution should be taken not to over-tighten the hemostatic adapter around the balloon catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.
5	Advance the balloon catheter and guidewire assembly until the proximal marks align with the hemostatic adapter hub. This indicates that the balloon catheter tip has reached the guide catheter tip.
6	Slowly rotate the guidewire while advancing through the artery until crossing of the stenosis by angiographic assessment.
7	Advance the balloon catheter over the guidewire and position the balloon relative to the lesion to be dilated; inflate the balloon to the appropriate pressure. If difficulty is experienced during balloon inflation, do not continue use; remove the device and do not attempt to use it. **BALLOON PRESSURE MUST NOT EXCEED THE RATED BURST PRESSURE.**

Note: Refer to **Table 1** or to the balloon compliance chart included with labeling.

REMOVAL PROCEDURE

Step	Action
1	After angioplasty is complete, deflate the balloon. Before withdrawing the device, visually confirm complete balloon deflation by fluoroscopy. If difficulty is experienced deflating, connect a large-barrel syringe and manually deflate the device.
2	Withdraw the balloon catheter until it is clear of the lesion. Maintain the guidewire across the dilated stenosis.
3	Perform angiography using the guide catheter as an angiographic catheter to confirm dilation.

4 After angiography has confirmed that the lumen of the dilated artery has not acutely occluded, slowly withdraw the guidewire and the deflated balloon from the guide catheter and through the adapter. Tighten the hemostatic adapter knob.

Note: After the deflated balloon catheter is withdrawn, if reinsertion is necessary, it should be wiped clean with sterile heparinized normal saline and stored in a basin of the same solution until reinsertion.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning and sterilization of the device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the device and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this device and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. BSC assumes no liability with respect to device reused, reprocessed or resterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use with respect to such device.

Symbol Translation Key:

CONT: Content

This Product Contains No Detectable Latex.
本製品は検出可能なラテックスを含有しない。

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Instructions for Use

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90163966-01 Rev. B

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Instructions for Use

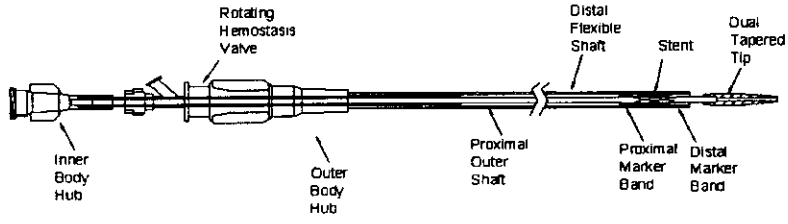
Humanitarian Device: The Wingspan Stent System with Gateway PTA Balloon Catheter is Authorized by Federal law for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system.

The effectiveness of this device for this use has not been demonstrated.

DEVICE DESCRIPTION

The Wingspan Stent System includes:

- A self-expanding, nitinol Stent with four radiopaque markerbands on each end (distal and proximal).
- A flexible over-the-wire Stent Delivery System (Inner Body and Outer Body) with pre-loaded Stent.
- The Wingspan Stent System is used in conjunction with the Gateway PTA Balloon Catheter.



INDICATION FOR USE

The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system.

CONTRAINDICATION

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Lesions that are highly calcified or otherwise could prevent access or appropriate expansion of the Stent.

WARNINGS

- The Wingspan Stent System with Gateway PTA Balloon Catheter should only be used by physicians who have received appropriate training in interventional neuroradiology and treatment of intracranial atherosclerotic disease.
- The Wingspan Stent System is not designed or intended for contrast injections or injections other than heparinized saline.
- If excessive resistance is encountered during the use of the Wingspan Stent System or with the Gateway PTA Balloon Catheter at any time during the procedure, discontinue use of the System. Movement of the System against resistance may result in damage to the vessel, or a System component.
- In animal evaluations, the severity of vessel stenosis/neointimal thickness appears to be correlated with the degree of trauma inflicted on the arterial walls by Stent placement or Stent radial expansion.
- Experience with stent implants indicates that there is a risk of restenosis. Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The risks and long-term outcome following repeat dilation of endothelialized stents is unknown at present.
- If the stent is implanted adjacent to or contacting other implanted metal, such as another stent or embolic coil, the metals should be of similar composition to avoid galvanic corrosion potential.

PRECAUTIONS

General Precautions

- The Wingspan Stent System and the Gateway PTA Balloon Catheter are provided STERILE for single use only. Do not resterilize. Store in a cool, dry place.
- Use the Wingspan Stent System and Gateway PTA Balloon Catheter prior to the "Use By" date printed on the package.
- Select a Stent size (length and diameter) that extends a minimum of 3mm on both sides of the lesion.

Preparation Precautions

- Carefully inspect the sterile package and Wingspan Stent System prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.
- Typical antiplatelet and anticoagulation regimen used for interventional intracranial procedures is an important adjunct to Stent treatment. Patients must be advised to take their prescribed medications after the Stent is implanted and should be counseled on the risk of not complying with medical therapy. In-stent thrombosis may occur during the procedure if proper antiplatelet and anticoagulation therapy is not administered.
- Do not steam shape the tip of the Wingspan Stent System because it could damage the Stent or Delivery System.

Procedure Precautions

- Implanting a Stent may lead to dissection of the vessel distal or proximal to the Stent and may cause other complications (vasospasm/acute closure) of the vessel requiring additional intervention (i.e., further dilation, placement of stents).
- Do not deploy the Stent if it is not properly positioned in the vessel.
- Placement of the Stent may compromise side branch patency.
- Follow the Wingspan Stent System preparation and use instructions carefully.
- Previous studies have shown that some metal stents may be incompatible with MRI scanning. The Wingspan Stent System has been shown to be MRI compatible in MRI systems operating at field strengths of 3.0 Tesla or lower. MRI laboratory evaluation demonstrated that no significant image distortion or heating was created by the presence of the Stents at scanning sequences commonly used during MRI procedures.
- Do not use the Wingspan Stent System or the Gateway PTA Balloon Catheter for repositioning or recapturing the Stent.
- Exercise caution when crossing the deployed Stent with guidewires or other devices.
- In tortuous vessels, a stiff guidewire may cause binding within the Wingspan Stent System or the Gateway Balloon Catheter during deployment. In such cases, use only soft guidewires, and position the floppy section of the guidewire within the Stent.
- After deployment, the Stent may foreshorten up to 2.4% in 2.5 mm Stents and up to 7.1% in 4.5 mm Stents.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vasculature and/or the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.

ADVERSE EVENTS

Observed Adverse Events

A clinical study was conducted on 45 patients with intracranial atherosclerotic disease at 12 international sites. Data are presented on 44 patients through 30 days and on 42 patients who have reached the 6-month follow-up visit. **Table 1** summarizes the adverse events observed in the clinical study.

Table 1 –Adverse Events

Event	N=45		Time of Occurrence		
	N	%	Procedure[1]	<30 days	>30 days
Infection	9	20.0	0	7	2
TIA	7[2]	15.6	0	1	6
Stroke	5	11.1[3]	0	2[4]	3[5]
Hematoma	6	13.3	3	2	1
Vasospasm	5	11.1	5	0	0
Hemorrhagic Event	4	8.9	0	2	2
Hypertension	4	8.9	3	0	1
Peripheral vascular diseases	4	8.9	0	0	4
Neurological symptoms	3	6.7	1	1	1
Pain	3	6.7	0	3	0
AMI	2	4.4	0	1	1
Angina	2	4.4	0	2	0
Arrhythmia	2	4.4	1	0	1
Creatinine increase	2	4.4	0	1	1
Hematuria	2	4.4	0	2	0
Hypoglycemia/hyperglycemia	2	4.4	1	1	0
Asymptomatic Thromboembolic Event	1	2.2	1	0	0
Bradycardia (35 min)	1	2.2	0	1	0
Broken middle-foot left/V-fracture	1	2.2	0	0	1
Chronical antrum gastritis	1	2.2	0	0	1
Death	1	2.2	0	1	0
Elevated bilirubin, GOT, GPT[6]	1	2.2	0	1	0
Fever	1	2.2	1	0	0
Hiatus hernia	1	2.2	0	0	1
Hypervolemia	1	2.2	1	0	0
New distal in stent stenosis[7]	1	2.2	0	0	1
Pulmonary edema	1	2.2	0	1	0
Respiratory failure[8]	1	2.2	1	0	0
Seizure	1	2.2	0	1	0
Syncope	1	2.2	0	1	0

(1) Procedural events were those occuring within 24 hours of the procedure (day 0).
(2) Seven TIAs occurred in 6 patients.
(3) Five strokes occurred in four patients. Four strokes were adjudicated as ischemic stroke, and one as a hemorrhagic stroke.
(4) Both events were adjudicated as major ipsilateral stroke. One of these was a hemorrhagic stroke, and the patient later died. The other was an ischemic stroke from which the patient recovered.
(5) All three events were ischemic strokes. One event was adjudicated as ipsilateral and minor. The remaining two events were adjudicated as contralateral, one major and the other minor.
(6) Due to unknown reasons
(7) This patient was implanted with a coronary stent after experiencing TIA but without CT scan evidence of a new infarction. Angiographic results indicated an in-stent stenosis of >90% distal to the previously treated lesion.
(8) Due to epiglottic edema caused by an unknown allergic reaction.

Potential Adverse Events

Potential adverse events that were not observed in the clinical study, but that , may be associated with the use of the Wingspan Stent System with Gateway PTA Balloon Catheter or with the procedure include:

Cerebral aneurysm
Coagulopathy
Emboli (air, tissue, or thrombotic tissue)
Intimal dissection
Pseudoaneurysm
Stent migration
Stent misplacement
Stent occlusion
Stent embolization
Stent thrombosis
Vessel perforation
Vessel rupture
Vessel thrombosis
Vessel trauma requiring surgical repair or intervention

CLINICAL EXPERIENCE

This study was a prospective, multi-center, single-arm trial of 45 patients enrolled at 12 international centers. Patients were considered eligible if they had presented with evidence of recurrent stroke, refractory to medical therapy and thought to be secondary to intracranial stenosis >50%. For the purpose of the study inclusion criteria, recurrent stroke was defined as patients with stroke history, treated with medical therapy, who remain symptomatic at enrollment screening. The study did not include a control group because no alternative standard therapy was readily available for this disease state. The results from this study were compared with historical controls based on literature published in peer-reviewed journals pertaining to a similar cohort of patients.

The objective of the study was to evaluate the safety and feasibility of the Wingspan Stent System with Gateway PTA Balloon Catheter for the treatment of symptomatic atherosclerotic lesions in the intracranial arteries. Patients were evaluated with a neurological examination and cerebral angiography preoperatively, with a cerebral angiography immediately postoperatively, with a neurological examination prior to hospital discharge and at 30-day follow-up, and with a neurological examination and cerebral angiography at 6 months post-procedure.

The primary safety endpoint was composite ipsilateral stroke/death at 30 days. Changes in the target vessel were evaluated angiographically. Procedure success was defined as Stent success without stroke or death at discharge. Safety was evaluated by the incidence of adverse events at discharge, 30-day follow-up, and 6-month follow-up.

The study was considered complete, with respect to the primary endpoint, after 30 evaluable patients completed the 30-day follow-up evaluation. However, all enrolled patients were to have a follow-up digital subtraction angiogram and neurological exam at 6 months. Evaluable patients were those who met eligibility requirements for primary endpoint assessment and who received a Stent.

Patient Data Available

Of the 45 patients enrolled, 44 were treated with the Wingspan Stent System with Gateway PTA Balloon Catheter and were considered evaluable patients. All 45 patients were followed through discharge. One patient was enrolled but not treated due to problems with access through the patient's tortuous anatomy. One patient died ten days post-procedure from cerebral hemorrhage, and 44 were followed through 30-day follow-up. Of these, 42 patients were followed through 6 months with clinical and neurological examinations, and 40 patients were followed through 6 months with post-operative angiographic assessment of the treated lesions. Patient demographics are listed in **Table 2**, patient neurological history is listed in **Table 3**, and patient medical history is listed in **Table 4**.

Table 2 – Patient Demographics

Patient Characteristics	N=45
Age (Years)	
Mean ± SD	66 ± 8
Median	65
Range (min, max)	47 , 81
Male	73.3% (33/45)
Ethnicity	
Caucasian	73.3% (33/45)
Asian	26.7% (12/45)

Table 3 – Neurological History

Neurological History	N=45	
	N	%
Stroke	43	95.6
Transient Ischemic Attacks	13	28.9
Other Neurological Diseases	35	77.8

Table 4 – Medical History

Medical History	N=45	
	N	%
Hypertension	41	91.1
Hypercholesterolemia/Hyperlipidemia	26	57.8
Smoking	24	53.3
Diabetes	24	53.3
Angina/Coronary Artery Disease	10	22.2
Peripheral Artery Disease	6	13.3
Arrhythmia	4	8.9
Congestive Heart Failure	3	6.7
Renal Failure	2	4.4
Myocardial Infarction	1	2.2
Liver Dysfunction	1	2.2

Table 5 summarizes the data from the investigators regarding lesion locations. A total of 44 intracranial atherosclerotic lesions were treated in 45 patients. Twenty-three (51.1%) of the lesions were located in the anterior circulation, and 22 (48.9%) were located in the posterior circulation.

Table 5 – Lesion Location

Location	N=45	
	N	%
Carotid petrous artery	5	11.1
Carotid cavernous artery	4	8.9
Carotid ophthalmic artery	1	2.2
Posterior communicating artery	1	2.2
Supraclinoid carotid artery	1	2.2
Carotid bifurcation	1	2.2
Middle cerebral artery (M1)	10	22.2
Vertebral artery	13	28.9
Basilar trunk	9	20
Total	**45**	**100**

Primary Safety Endpoints

The results of the study indicated that the Gateway PTA Balloon Catheter could be inflated safely to dilate the lesion, and the Stent could be deployed safely across the target lesion (44/45 lesions, 97.8% successfully accessed). The primary endpoints for safety were composite ipsilateral stroke or death at 30 days. The data are presented below for the evaluable patient populations (N=44) in **Table 6**.

Table 6 – Primary Endpoints: Stroke or Death (Evaluable Patients)

Endpoints (30 Day)*	(N=44)	
	N	%
Death or Ipsilateral stroke** (composite)	2	4.5
Major Ipsilateral stroke#	2	4.5
Death	1	2.3

* Results were based on adjudication by the Clinical Events Committee (CEC)

** Ipsilateral stroke is defined as events that occurred in the same hemisphere of the target lesion

#Major stroke is defined as NIHSS $\geq$15, MRS $\geq$4, or BI $\leq$60, where NIHSS is the National Institute of Health Stroke Scale, MRS is Modified Rankin Scale, and BI is Barthel Index

Secondary Endpoints

The secondary endpoints in this study include incidence of parent vessel dissection, symptomatic restenosis, Stent migration, access site complications requiring treatment, and clinical outcomes of stroke and death at 6 months. No parent vessel dissections or Stent migration were reported at immediate post-implant or at 6-month follow-up. There were four reported incidents of access site complications requiring treatment. Five patients developed seven access site-related adverse events, but only four events required treatment.

Table 7 summarizes the secondary endpoints for safety of composite ipsilateral stroke or death at 6-month follow-up. A total of 42 patients had 6-month follow-up and are included in this analysis.

TABLE 7 – Incidence of Stroke or Death at 6-Month Follow-Up (Clinical Follow-Up)

Endpoints at 6 Months (Evaluable Patients)*	(N = 42)**	
	N	%
Death or ipsilateral stroke (composite)	3	7.1
Ipsilateral stroke#	3	7.1
Major ipsilateral stroke^	2	4.8
Minor ipsilateral stroke	1	2.4
Contralateral stroke	1	2.4
Major contralateral stroke^	1	2.4
Minor contralateral stroke	0	0.0
Death	1	2.4
All-cause stroke	4	9.5
Major all-cause stroke^	3	7.1
Minor all-cause stroke	1	2.4

* Results were based on adjudication by the CEC

** At 6 months, 2 of the 44 patients were lost to follow-up

Ipsilateral stroke is defined as events that occurred in the same hemisphere of the target lesion

^ Major stroke is defined as NIHSS ≥15, MRS ≥4, or BI ≤60 where NIHSS is the National Institute of Health Stroke Scale, MRS is Modified Rankin Scale, and BI is Barthel Index

Table 8 below compares the angiographic results between treatment and 6-month follow-up. At trial's end, 40 patients were examined angiographically at 6 months.

Table 8 – Angiographic Treatment Results at 6-Month Follow-Up

Measure	Baseline (N=45)	Post PTA (N=44)	Post Stent (N=44)	6 Months* (N=40)
Reference Vessel Diameter (mm)				
Mean ± SD	3.1 ± 0.8	3.2 ± 0.8	3.2 ± 0.8	3.1 ± 0.8
Median	3.1	3.2	3.2	3.1
Range (min, max)	(1.3 , 4.8)	(1.3 , 4.8)	(1.3 , 4.8)	(1.3 , 4.8)
MLD at Target Lesion (mm)**				
Mean ± SD	0.8 ± 0.6	1.6 ± 0.6	2.1 ± 0.5	2.2 ± 0.8
Median	0.8	1.6	2.0	2.1
Range (min, max)	(0.0 , 2.0)	(0.5 , 2.9)	(1.3 , 3.2)	(0.4 , 4.0)
Gain in MLD from Baseline (mm)				
Mean ± SD		-0.8 ± 0.6	-1.3 ± 0.6	-1.4 ± 0.7
Median		-0.7	-1.2	-1.4
Range (min, max)		(-3.0 , 0.2)	(-3.5 , -0.2)	(-3.5 , -0.0)
% Stenosis				
Mean ± SD	74.9 ± 9.8	50.0 ± 16.2	31.9 ± 13.6	28.0 ± 23.2
Median	75.0	53.0	33.0	30.0
Range (min, max)	(57.0 , 99.0)	(0.0 , 79.0)	(-8.0 , 49.0)	(-33.0 , 81.0)
Change in % Stenosis from Baseline				
Mean ± SD		24.8 ± 19.5	43.0 ± 18.6	47.8 ± 25.6
Median		22.5	39.0	42.0
Range (min, max)		(-5.0 , 88.0)	(18.0 , 107.0)	(2.0 , 116.0)
≥50% Stenosis	100% (45/45)	54.5% (24/44)	0.0% (0/44)	7.5% (3/40)

* Of the 44 evaluable patients, 40 patients were available for angiographic follow-up

** MLD – Minimum Lumen Diameter

A comparison of the stroke rates in the SSYLVIA study to those in the Wingspan study are summarized in **Table 9**. The SSYLVIA study was a prospective, single arm study of angioplasty and balloon expandable stenting of intracranial atherosclerotic disease in patients with a history of stroke or TIA. From the small number of patients studied, it appears that the Wingspan study results are similar to those reported for the SSYLVIA study.

Table 9 –Stroke Rate Comparison (SSYLVIA* vs. Wingspan)

Clinical Study	Follow-Up	All Stroke	Death	All Stroke and Death	Ipsilateral Stroke
SSYLVIA n=61	Mean: 216 days (n=48 at 6 months)	13.1% (8/61)	6.6% (4/61)	13.1% (8/61)	11.5% (7/61)
Wingspan n=45	Mean: 174 days (n=42 at 6 months)	9.5% (4/42)	2.4% (1/42)	9.5% (4/42)	7.1% (3/42)

* Food and Drug Administration, CDRH SSYLVIA Study NEUROLINK® System Summary of Safety and Probable Benefit page. Available at: http://www.fda.bov/cdrh/pdf/H010004b.pdf . Accessed January 19, 2005.

PROCEDURE STEPS

Angiographic Assessment of Lesion and Stent Selection

1. Using angiography, determine the location and size of the lesion and vessel diameter. Careful Stent sizing is important to successful Stenting. In general, the Stent size should be chosen to match the normal vessel diameter adjacent to the lesion.

2. Select a Stent length that is at least 6mm longer than the lesion to extend a minimum of 3 mm on both sides of the lesion. Stent sizing guidelines for each Stent diameter are given in **Table 10**.

3. Select a Balloon size to match the lesion length and no more than 80% of the reference vessel diameter, allowing for vessel dilation up to but no more than the vessel diameter proximal and distal to the lesion. (See Gateway PTA Balloon Catheter *Instructions for Use*.)

Wingspan Stent System Preparation

1. Open the pouch to remove the packaging tray, and inspect for compromised packaging.

2. Flush the dispenser hoop with sterile heparinized saline, carefully pull out the proximal hub assemblies from tray, tighten the rotating hemostasis valve onto the Inner Body, and remove the Delivery System. Inspect Delivery System for damage, such as kinks. The Stent should be preloaded into the distal tip of the Delivery System.

3. Connect a rotating hemostasis valve to the hub of the Delivery System Inner Body, and flush the lumen of the Delivery System Inner Body with sterile, heparinized saline.

4. Loosen the Delivery System Outer Body rotating hemostasis valve, flush the Delivery System Outer Body with heparinized saline, and tighten the hemostasis valve onto the Delivery System Inner Body.

5 Continue to flush the Delivery System Outer Body to purge air from the system.

6 Connect the hemostasis valve side port of the Delivery System Outer Body and Delivery System Inner Body to a pressurized sterile heparinized saline flush.

7 Loosen the hemostasis valve on the Delivery System Outer Body that is locked onto the Delivery System Inner Body, and gently retract the Delivery System Inner Body so that there is a 1-2 mm gap between the proximal end of the dual tapered tip and the distal end of the Outer Body. This should result in a rapid saline drip from the Outer Body tip.

Note: Do not use excessive force or lodge the Inner Body tip inside the Delivery System.

8 Tighten the Delivery System Outer Body hemostasis valve around the Delivery System Inner Body to hold the Delivery System Inner Body in place during advancement of the Wingspan Stent System.

Gateway PTA Balloon Catheter Preparation

1. Prepare the Gateway PTA Balloon Catheter as outlined in the Gateway PTA Balloon Catheter *Instructions for Use*.

Guidewire Positioning

1. Position an access guidewire across the lesion using standard microcatheter and guidewire techniques. Recommended guide catheter specifications include a minimum 90cm length and 0.064in ID.

2. Replace the access guidewire with an exchange length 0.014in guidewire, and remove the microcatheter. Leave the exchange length guidewire across the lesion. Soft guidewires are recommended rather than support guidewires.

Balloon Deployment

1. Insert the Gateway PTA Balloon Catheter over the guidewire and pre-dilate the lesion as described in the *Instructions for Use*. (See Gateway PTA Balloon Catheter *Instructions for Use*). Ensure that Balloon inflation does not exceed 80% of the reference vessel diameter (proximal or distal to the lesion, whichever is smaller).

Stent Positioning and Deployment

1. Carefully backload the Wingspan Stent System onto the 0.014in guidewire through the Delivery System.

2. Carefully advance the Wingspan Stent System into the guide catheter.

3. Open the guide catheter hemostasis valve. Under fluoroscopic guidance, advance the Wingspan Stent System over the guidewire until the Stent is slightly distal to the target lesion site (use the four distal radiopaque markerbands to identify the Stent position). See **Figure 1, Delivery Catheter Advancement**.

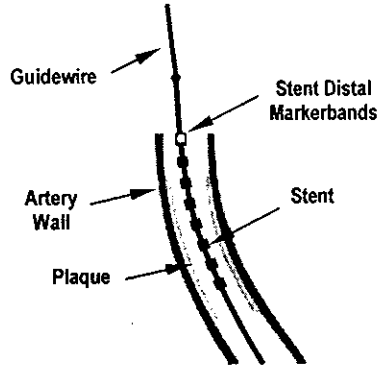


Fig 1 – Delivery Catheter Advancement

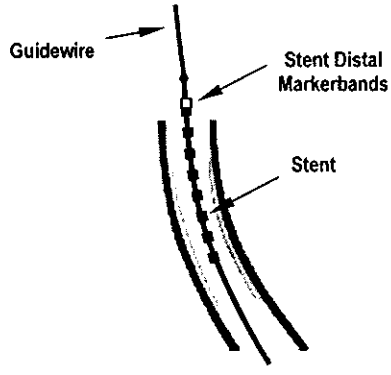


Fig 2 – Stent Pre-Deployment Alignment

4. Loosen the Delivery System Outer Body rotating hemostasis valve, and advance the Delivery System Inner Body until the proximal radiopaque markerband bumper is just proximal to the Stent. Tighten the Outer Body rotating hemostasis valve. See **Figure 2, Stent Pre-Deployment Alignment**.

5. Slightly withdraw the hub of the Delivery System Outer Body until the Stent is directly aligned with the target lesion site. Pull back on the Delivery System to make the final adjustment for Stent positioning. This will ensure that slack has been removed from the Delivery System just prior to deployment See **Figure 3, Stent Positioning**.

6. The Stent is now ready to be deployed.

NOTE: **The best fluoroscopic view for positioning the Stent for deployment is the view that shows the vessel distal to the lesion. This view may not be the same view as that used as the working position for Stent deployment.**

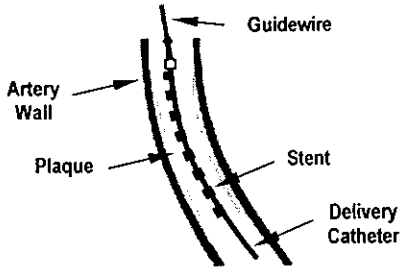


Fig. 3 – Stent Positioning

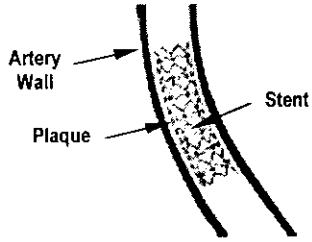


Fig. 4 – Deployed Stent

7. Loosen the rotating hemostasis valve on the Delivery System Outer Body. Deploy the Stent by holding the Delivery System Inner Body Hub stationary with one hand while continuing to carefully withdraw the hub of the Delivery System Outer Body hub with the other hand. This will deploy the Stent.

8. As the Stent deploys, you will see the markerbands on the distal end of the Stent spread out from one another. This is the Stent opening. Continue deploying the Stent in a continuously smooth motion. Do not attempt to move the Stent after deployment has begun. Be careful to not advance the Delivery System Outer Body as the Stent is deploying. See **Figure 4, Deployed Stent.**

9. After the Stent is completely deployed, tighten the Delivery System Outer Body rotating hemostasis valve, and gently remove the Wingspan Stent System. If excessive friction is experienced during removal of system, loosen the Delivery System Outer Body rotating hemostasis valve, and pull the Delivery System Inner Body Hub back so the tip is in contact with the Delivery System Outer Body tip. Tighten the rotating hemostasis valve and remove the Delivery System.

TABLE 10 – Wingspan Stent System
Recommended Sizing Guidelines

Labeled Stent Diameter	Labeled Stent Length[1] (mm)	Self-Expanded Stent Diameter[2]	Recommended Vessel Diameter[3] (mm)	Delivery System Useable Length	Maximum Guidewire Diameter	Minimum Guide Catheter ID
2.5 mm	9 mm	2.8 mm	>2.0 and ≤2.5	135 cm	0.014 in	0.064 in
	15 mm					
	20 mm					
3.0 mm	9 mm	3.4 mm	>2.5 and ≤3.0			
	15 mm					
	20 mm					
3.5 mm	9 mm	3.9 mm	>3.0 and ≤3.5			
	15 mm					
	20 mm					
4.0 mm	9 mm	4.4 mm	>3.5 and ≤4.0			
	15 mm					
	20 mm					
4.5 mm	9 mm	4.9 mm	>4.0 and ≤4.5			
	15 mm					
	20 mm					

[1]Select a Stent length that is at least 6mm longer than the lesion to extend a minimum of 3mm on both sides of the lesion.
[2]Stent will not expand beyond the self-expanding diameter.
[3]Select a Stent diameter based both on the sizing recommendations in this table and on the larger vessel diameter (proximal or distal reference vessel diameter).

QUESTIONS AND ANSWERS

Q: The Wingspan Stent System seems to be binding with the guidewire, making it difficult to advance the System. What should I do?

A: Use soft guidewires rather than support guidewires because soft guidewires facilitate maneuverability of the Wingspan Stent System and deployment of the Stent. Excess tension can build up in the guidewire resulting in increased friction in the System. Alleviate the friction by slightly retracting the guidewire and Delivery System to remove any accumulated tension. If excessive friction continues, confirm that the Delivery System saline flush is functioning. With use, guidewires can become kinked and lose their lubricious coatings. If excessive friction persists, consider removing and discarding the guidewire and Wingspan Stent System and replacing them with new devices.

Generally, once the Wingspan Stent System is tracking forward over the guidewire, take advantage of the momentum and continue tracking to a target site that is distal to target lesion. It is easier to move the Wingspan Stent System from a distal to proximal location across the target lesion instead of trying to reposition it by advancing the Wingspan Stent System.

Q: Which Stent size should I choose if I intend to place the Stent in a vessel that has a different diameter between the proximal and distal ends of the Stent? Example: *Vessel increases from 2mm PCA (posterior communicating artery) to a 3.4mm basilar.*

A: Choose the Stent sized for the larger vessel. In this example, choose the 3.5mm Stent. This Stent can be deployed safely in the smaller PCA and will be well anchored in the basilar artery.

Q: I have accidentally started to deploy the Stent, but it is not in the location that I wanted. What should I do?

A: The safest course of action generally is not to try repositioning the Stent, but to continue to deploy the Stent where it is, and then deploy a second Stent at the desired location. Safely deploying a Stent, even in an undesired location will minimize vascular injury. Animal studies have demonstrated that the Stent endothelializes in less than 30 days.

Q: I misjudged the positioning of the Stent and have deployed it with one end adjacent to the target lesion rather than in the normal part of the parent vessel? What should I do?

A: Leave the guidewire in place, remove the Delivery System, and insert and deploy a second Stent starting from inside from the first Stent to the normal portion of the parent vessel (telescoping Stents). The second Stent should be of the same diameter or larger than the first.

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Symbol Translation Key:

CONT: Content

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